



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/807,489 | 03/23/2004 | Matsuhiko Nishizawa | 20075600-0014 | 3061 |
| 29932 7590 05/22/2008 PAULA EVANS/ C/O SONNENSCHN NATH & ROSENTHAL LLP P.O. BOX 061080 WACKER DRIVE STATION, SEARS TOWER CHICAGO, IL 60606-1080 | | | | |
| EXAMINER LILLING, HERBERT J | | | | |
| ART UNIT | | PAPER NUMBER | | |
| 1657 | | | | |
| MAIL DATE | | DELIVERY MODE | | |
| 05/22/2008 | | PAPER | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/807,489

Applicant(s)

NISHIZAWA ET AL.

Examiner

HERBERT J. LILLING

Art Unit

1657

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 March 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7-17 and 22-34 is/are pending in the application.
- 4a) Of the above claim(s) 10-12, 16, 18-21 and 34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7-9, 13-15, 17 and 22-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 10-12, 16, 18-21 and 34 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 March 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 07-27-2004
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

1. Receipt is acknowledged of an election and amendment filed March 03, 2008.

2. Claims 7-17 and 22-34 are now pending in this application.

Claims 1-6 and 18-21 have been cancelled.

3. Attorney David Metzger has elected "one enzyme and an electrode"
Claims 7-9, 13-15, 17, and 22-33.

Claims 10-12, 16, 18-21 and 34 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on March 03, 2008.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7-9, 13-15, 17 and 22-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miki et al , Analytical Sciences, 1989, 5(3), 269) further in view of Kawabata Yuji ,JP 2000-133297, May 12, 2000 [see spec Page 2].

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Miki et al., teaches a species within the scope of Claim 7 which recites the following:

"An electrode comprising a mediator, said mediator comprising a quinone molecule derivative, wherein the mediator is immobilized and the mediator mediates electron transfer between at least one enzyme and an electrode." ;

which art teaches quinone discloses the preferred species 2-methyl-1,4-naphthoquinone (VK3) as a mediator and NAD⁺ as well as, diaphorase and dehydrogenase enzymes.

The reference does not disclose the immobilizing the enzyme.

Reference Kawabata Yuji , JP 2000-133297, teaches a naphthoquinone as a mediator for a biofuel cell whereby the enzyme is immobilized on an electrode for reducing an amount of the mediator used so that diffusion of the mediator in an electrode solution does not become rate controlling.

Thus, it would have been prima facie obvious to one of ordinary skilled in the art to employ immobilization of the enzyme as mediator of Miki et al in view of the advantages as taught by the disclosure of Yuji , JP 2000-133297.

Claims 8 and 9 requires at least one enzyme and diaphorase as the enzyme which are disclosed by above reference(s).

Claim 13 further requires crosslinking agent and polymer which are disclosed by the disclosure of **JP 2000-133297**

Claims 14-15 are not disclosed by the references.

Claim 17 is an intended use which the references render the apparatus unpatentable absent a showing to the contrary that the reference apparatus cannot be employed "used for one of a biofuel cell and a biosensor".

Claim 22-23-24 is the same as VK3 of the reference.

Claims 25-33 have been modified which modification would have been prima facie obvious absent patentable differences between the reference(s).

Further in light of the Supreme Court's recent decision in KSR International Co. v. Teleflex Inc (TFX) ., 82 USPQ2d 1385 (2007) based on the reasoning may still include the established Court of Appeals for the Federal Circuit standard that a claimed invention may be obvious if the examiner identifies a prior art teaching, suggestion, or motivation (TSM) to make it, however, the Guidelines explain that there is no requirement that patent examiners use the TSM approach in order to make a proper obviousness rejection. **Furthermore, the Guidelines point out that even if the TSM approach cannot be applied to a claimed invention, that invention may still be found obvious.**

If there are any differences with respect to the crosslinking polymer, or functional groups to attach the polymer or the specific naphthoquinone molecule, these differences would have been prima facie obvious absent unexpected **or unobvious patentable processes or results**. It would have been reasonable for one of ordinary

Art Unit: 1657

skilled in the art having the references in front of this skilled worker to reasonable expect that the references would have been obvious based on the broad disclosure especially those of the above two references.

Examiner will consider any reasonable showing in the specification, arguments, additional showings commensurate in scope with the specification or amendments to overcome the references prior to any final rejections.

5. **No claim is allowed.**

6. Figures 1 and 8 contain Japanese markings which should be changed or deleted.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Lilling whose telephone number is 571-272-0918 and Fax Number is **571-273-8300**. or SPE Jon Weber whose telephone number is 571-272-0925. Examiner can be reached Monday-Friday from about 7:30 A.M. to about 7:00 P.M. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

H.J.Lilling: HJL
(571) 272-0918
Art Unit 1657

/HERBERT J LILLING/
Primary Examiner, Art Unit 1657